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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,111	11/05/2001	Gerard Bernard O'Beirne	PA-0060	7469

7590

05/31/2005

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EXAMINER

GABEL, GAIENE

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 05/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/992,111

Applicant(s)

O'BEIRNE ET AL.

Examiner

Gailene R. Gabel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 2-4 and 14-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 5-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-13 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 11, 2005 has been entered.

### ***Amendment Entry***

2. Applicant's amendment and response filed on March 11, 2005 is acknowledged and has been entered. Claim 1 has been amended. Claims 2-4 and 14-19 remain withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being claims drawn to a non-elected invention. Currently, claims 1-19 are pending. Claims 1 and 5-13 are under examination.

### ***Rejections Withdrawn***

3. Any rejections not reiterated herein from the previous Office Actions, have been withdrawn.

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4. In light of Applicant's amendment and argument, the rejection of claims 1 and 5-13 under 35 U.S.C. 102(e) as being anticipated by Jessop (US Patent 6,524,786 B1) is hereby, withdrawn.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is ambiguous in reciting, "cellular process is performed in real time using non-invasive technique" because it is unclear how cellular process such as metabolism and death can be *performed* in real time using non-invasive technique. Does Applicant intend, "wherein said detection of cellular process can be performed in real time using non-invasive technique."

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1 and 5-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jessop (US Patent 6,524,786 B1) in view of Clapper et al. (US Patent 5,512,474).

Jessop discloses scintillation proximity assays performed in multiwell plates wherein a charge-coupled device (CCD) is used in a detection step to image cellular processes in living and growing (proliferating) cells (see Abstract, column 2, line 59 to column 3, line 11, and column 4, lines 4-37). Jessop teaches providing one or more different populations of living, growing, and adherent cells which are attached to support particles (particulates or beads) and carrying a scintillant substance (phosphor). In

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practice, Jessop teaches introducing the adherent cells attached to scintillant particles in a medium, to massive surfaces such as separate vessels or wells of a microtiter plate (see column 3, lines 12-25 and lines 52-66). Thereafter, radioisotope-labeled reagent is added to the wells so as to monitor uptake (association) of the radioisotope by the growing culture cells in real time or dynamic mode. The radioisotopes include  $^3\text{H}$ ,  $^{125}\text{I}$ ,  $^{14}\text{C}$ ,  $^{35}\text{S}$ ,  $^{56}\text{Ca}$ ,  $^{33}\text{P}$ ,  $^{32}\text{P}$ ,  $^{55}\text{Fe}$ ,  $^{86}\text{Rb}$ ,  $^{109}\text{Cd}$ , and  $^{51}\text{Cr}$  (see column 3, lines 45-51 and Example 7). In Example 9, Jessop monitors uptake of  $^{14}\text{C}$  thymidine in growing (proliferating) cells seeded on the surface of a microwell plate in a thymidine uptake assay. Cellular processes are measured by detecting light emission from the scintillant support particles as caused by the radioactive decay of the radioisotope label (see column 3, lines 26-44). The cellular processes tested include receptor binding assay, uptake, and biochemical response. Different concentrations of radioisotope label are incubated with different samples of cells in reaction vessels (see column 3, lines 64-67 and Examples 1, 6, and 7). Jessop provides that detection step may be performed by scintillation counting (see column 1, lines 47-60).

Jessop differs from the instant invention in failing to teach that the scintillant support particles are adapted to support cell growth.

Clapper et al. disclose cell culture support particles which may be in the form of porous beads. Clapper et al. specifically teach combining a cell adhesion factor and a positively charged molecule such as polylysine or chitosan, for binding into the surface of the cell culture support particle to enable cell attachment and support or stabilize cell growth. See Abstract and columns 3-5, especially column 5, lines 54-65. Clapper et al.

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teach application of the cell culture support particles in scintillation vial assays and in quantitation of radiolabeled proteins immobilized into the cell culture support particles (see columns 14-15).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate a cell adhesion factor and a positively charged molecule such as polylysine or chitosan as taught by Clapper, for binding into the surface of the scintillant support particle in the method taught by Jessop in order to enable not only cell adherence, but also to support cell growth in the scintillant support particles because Clapper specifically showed applicability of the cell culture support particles in the field of scintillation assays and radioimmunoassay. One of ordinary skill in the art at the time of the instant invention would have been motivated to incorporate cell culture support as taught by Clapper into the method of measuring cellular processes as taught by Jessop because by supporting a cell growth capability in scintillant support particles, convenient and appropriate environmental conditions can be better controlled or altered for purposes of assaying for and measuring cellular processes as in the method taught by Jessop.

### ***Response to Arguments***

7. Applicant's arguments with respect to claims 1 and 5-13 have been considered but are moot in view of the new ground of rejection.

8. No claims are allowed.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gailene R. Gabel  
Patent Examiner  
Art Unit 1641  
May 25, 2005

*8/25/2005*